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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/750,427

12/31/2003

Frank Fago

L-F/217/273

1785

7590 02/25/2009
WOOD, HERRON & EVANS, L.L.P.
2700 Carew Tower
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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,427	Applicant(s) FAGO ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-21, 23 and 25-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-21, 23 and 25-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/22/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment filed on 12/22/08 has been entered.

Claims 9-21, 23, 25-37 are present for examination.

Claims 1-8, 22, 24 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-21, 23, 28-35 and 37 are rejected under 35 U.S.C. 103(a) as obvious over Duchon et al. (US 2004/0133165).

Regarding claims 9-11, 15-21, 23, 28, 30-35 and 37, Duchon clearly discloses the method for performing a filling sequence in a contrast media injector system comprising:

Attaching a fill tube to a syringe; that the retraction of plunger 412 (drawing contrast media into the syringe at a first rate 2ml/sec about 40 ml of media, as noted that the volume of 40 ml is not the maximum of volume, it can be filled up more than 40 ml). During the step of expelling substantially all air out, at least some of the contrast media is expelled through the fill tube (For example: Figs. 7B). Thereafter, filling the syringe at a second fill rate at faster rate (3 ml/sec) to fill the syringe with the desired fill volume of contrast media to complete the filling procedure (see para [0169]). Duchon does not specifically disclose that thereafter step of drawing contrast media into the syringe, then expelling substantially all air from the fill tube by expelling fluid from the syringe.

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However, at the point fill some contrast media into the syringe at first rate, there is some air with liquid contrast media in the syringe. The step of performing remove the substantially all air is inherently and well-known during the filling method, we do not want any air to be injected in to the body.

Furthermore, it would have been obvious to one skill in the art to include the step of expelling air from the syringe, by expelling fluid from the syringe, if one wished to make sure that all air bubbles were expelled from the syringe.

Regarding claims 12-14, 29 Duchon discloses a method for changing contrast media container during a syringe filing sequence, similarly to the method of claims 9-11 above, Duchon discloses a method comprising: attaching a fill tube to a syringe; thereafter, filling a syringe at least one of a first fill rate 2mm/Sec and a second fill rate 3ml/sec through the fill tube, the fill tube coupled between the syringe and a first contrast container (Fig. 1); the inherently-obvious step of pausing the filling when the contrast container is substantially empty, because, at this point, there is no contrast media left or running low on contrast media in the container. The system must be paused to replacing the second new bag /container of contrast media

Duchon discloses that the contrast fill operation is performed during initial set up of system 10, and maybe repeated during operation 10 whenever syringe body 18 is running low on contrast material (para [0062]). Duchon further discloses that: in automatic mode, subsequent to completion of an injection. In other words, the step of filling the contrast as described below (similar in claim 9) always happened before completion another injection. For example, these steps of claim 9 are: expelling substantially all air from the fill tube coupled between the syringe and the second contrast container wherein at least some of the contrast media is expelled from the syringe, through the fill tube, and into the second contrast container during the expelling; and thereafter, resuming filling the syringe from the second contrast container at the second fill rate that is faster than the first fill rate.

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Claims 25-27, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duchon et al. (US 2004/0133165) in view of Battiato et al. (US 5,925,022).

Duchon discloses the invention substantially as claimed. Duchon does not disclose the syringe oriented such that a discharge tip of the syringe is positioned above the barrel of the syringe during the filling, the expelling and the resuming.

Battiato discloses a method of filling the contrast media into the syringe including that the syringe is oriented such that a discharge tip of the syringe is positioned above the barrel of the syringe during the filling, expelling and the resuming (see Figs 13A-C, col. 19, line 49-col. 21, line 17).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the method of Duchon with a fill region, as taught by Battiato, in order to prevent of accidental injection of air into the subject.

Furthermore, it would have been obvious to a person of ordinary skill in the art to try to located the discharge tip of syringe positioned above the barrel of the syringe during the filling, the expelling and the resuming, to push the air out of the syringe as much as possible, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Response to Arguments

Applicant's arguments filed 12/12/08 have been fully considered but they are not persuasive.

1. Applicant argues that the para [0168-0169] stating is that one can fill a syringe slowly, until an air bubble in the syringe detaches from the plunger, and thereafter, fill faster. Duchon does not say that one should fill partially, then expel, then resume filling. That sequence is nowhere suggested in the text quoted above.

As we known, the contrast fill operation typically will result in some air being drawn into or remaining within syringe. It is very important, of course, to prevent air from being injected into the patient through the catheter/or needle. Therefore, the step of air purge operation or expel air out is inherently step. Duchon states, in para 0169, that using multiple speeds for retracting of plunger during syringe refill, an air forming bubble within syringe can be reduced more readily. The first rate occurs slowly about

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2ml/sec. At this point, there is some air formed in the syringe. Subsequence, a faster rate of about 3ml/sec is used to complete the filling procedure. In para 169, Duchon does not mention about the step expel the liquid after the step of filling the contrast at the first rate. However, at the point fill some contrast media into the syringe at first rate, there is some air with liquid contrast media in the syringe. The step of performing remove the substantially all air is inherently and well-known during the filling method, we do not want any air to be injected in to the body.

Furthermore, it would have been obvious to one skill in the art to include the step of expelling air from the syringe, by expelling fluid from the syringe, if one wished to make sure that all air bubbles were expelled from the syringe.

Not only that, Duchon also mentions that the step of filling the contrast fluid with contains trapped air at the first rate (Fig. 7B) is before the step of air has been expelled from syringe (Fig. 7C); and then filling the contrast at the second rate (Fig. 7D).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
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